UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,884	05/04/2005	Martin Purpura	5942/83615	4211

22242 7590 02/03/2010
FITCH EVEN TABIN & FLANNERY
120 SOUTH LASALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
02/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,884	PURPURA ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-52* is/are pending in the application.

4a) Of the above claim(s) *1-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/Remarks and amended claims filed on 11/13/09 is acknowledged.

Claims 1-34 have been cancelled.

New claims 35-52 have been added in this application.

Claims **35-52** are under prosecution.

The following are new rejections necessitated by new set of claims with new limitations.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 35-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Recitation of hydrophobic materials, polymers and mineral components in claim 35 makes the claim indefinite because metes and bounds of claim are not defined. Claim 35 recites the limitation derivatives thereof which make the claim indefinite

because the metes and bounds of claims are not defined. Appropriate correction is required.

DOUBLE PATENTING

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13-21 and 23-37 of copending Application No. 10/511885 Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending application and instant application have overlapping subject matter. The only difference is in particle size of instant application. Since the copending claims are also matrix, one would expect some particle size in copending application and optimization to the claimed size is a parameter which can be optimized.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants present that terminal disclaimer will be filed shortly, as such the rejection is maintained pending submission of the terminal disclaimer.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 35-38, 40-48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US pg pub 2003/0021881) in view of USP 6,312,719 and USP 6,426,069.

Friedman discloses homogeneous solid matrix containing proteins and lecithin (also known as phosphatidyl choline in the art), see abstract and examples. The reference teaches solid matrix of various shapes for administration of ingestible bioactive compounds, the composition has improved gastrointestinal dissolution and oral availability, see page 2, paragraph [0023]. The composition teaches lecithin (which is also known in the art as phosphotidylcholine), triglycerides and soybean, see page 2, paragraph [0092-0094] and 0078,.(thus the reference reads on acetone –insoluble phospholipid and supporting material). The reference teaches silica in the composition,

paragraph [0046] and vitamins and tocopherol in paragraph [0197]. Example 9 discloses fatty alcohol and lipid. The reference teaches polysaccharides in the composition, see paragraph [0012]. The amount of soybean lecithin is 0.5 gm to 1 gm in examples 19 and 20 which is more than 5% in the examples. The reference teaches utilizing wet granulation method for processing and extruding through the screen having openings of 0.5mm to 2.5mm and spheronized in a spheronizer, see paragraph 005. The reference teaches the homogeneous solid matrix swells in gastrointestinal tract and provides better bioavailability, see paragraph [0124].

The reference does not teach the lysophosphatidyl choline.

'719 teach treatment of atherosclerosis by utilizing lysophosphatidylcholine and teaches average diameter to be from 100-150 nanometers, see abstract. The reference teaches that besides clogging of blood vessels, atherosclerosis also causes damage to kidneys, intestines etc. see column 1, lines 30-35. The reference also teaches equivalency between phosphatidyl choline and other phospholipids which can be used to treat atherosclerosis, such as phosphatidylinositol, lysolecithin, and phosphatidylcholine, see column 6, lines 30-45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate lysophosphatidyl choline in the primary reference for better health benefits because '719 teaches equivalency between phospholipids and their corresponding lyso forms. One would thus have been motivated to utilize lysophosphatidyl choline in place of lecithin in the teachings of primary reference with an expectation to have improved nutritional product which provides better bioavailability

and gastrointestinal dissolution and also provides the improved physiological health benefits as taught by '719.

'069 teaches methods and compositions comprising lysophosphatidylcholine and lecithin and other phospholipids in treating intestinal absorption of fats which improves absorption of dietary fats, see column 2, lines 65-67 and column3, lines 1-2. The reference provides equivalency between various phospholipids and lysophospholipids such as phosphatidylcholine and lysophosphatidylcholine, see column2, lines 15-25.

It would have been obvious to have utilized lysophopshatidylcholine in place of lecithin and other phospholipids to have better intestinal absorption of dietary fats because '069 teaches and provides equivalency between various phospholipids. One of ordinary would have been further motivated to utilize lysophosphatidylcholine in a solid matrix of primary reference for better absorption, bioavailability and health benefits. From the teachings of the references, it is therefore apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Claims 35-38, 40-48 and 50-52 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kiliaan et al. (WO 01/84961 A2, presented in IDS) in view of Friedman (US pg pub 2003/0021881) and further in view of USP 6,312,719 and USP 6,426,069.

Kiliaan et al. discloses a nutritional preparation suitable for the prevention and/or treatment of **vascular disorders**, comprising long chain polyunsaturated fatty acids; phospholipids, the phospholipids contains at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol. The composition contains compounds which are a factor in methionine metabolism, containing at least one member selected from the group consisting of folic acid, vitamin B 12, vitamin B6, magnesium and zinc (mineral) see (abstract).

The preparation of the invention can be a pharmaceutical, dietetic as well as a nutritional preparation. The products can have the form of a liquid, powder, bar, cookie, sweetie, concentrate, paste, sauce, gel, emulsion, tablet, capsule, etc. to provide the daily dose of the bioactive components either as a single or in multiple doses (page 6, lines 1-5). Triglyceride (a hydrophobic material) is listed on page 6, line 14. The composition contains zinc and copper (see page 9, lines 1-5). Kiliaan et al. discloses on page 12, various diseases and symptoms that can be treated are cognitive degeneration (thus improving mental fitness) and improper functioning associated with kidneys, liver, stomach etc. Another advantage of the composition disclosed is in normalizing plasma cholesterol levels (see page 6, lines 17-18).

Kiliaan discloses a capsule containing phospholipids comprised of phosphatidyl serine and phosphatidylcholine (acetone insoluble phospholipids); the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids. The composition of Kiliaan is

administered to treat vascular disorders. The reference teaches that the composition can be in the form of tablet, powder, bar cookie or capsule, see page 6, lines 1-5. since the prior art teaches tablet and powder formulation, one would expect the matrix to be stable because prior art essentially teaches the claimed components.

While Killian teaches nutritional preparation can be in a tablet and powder form, Kiliaan does not specifically teach the claimed particle size.

Friedman as discussed above teaches a nutritional preparation comprising solid matrix with particle size from 0.5mm to 2.5 mm (500 micrometer to 2500 micrometer) and discloses that the composition has improved gastrointestinal dissolution and oral availability, see page 2, paragraph [0023].

It would have been obvious to one of ordinary skill in the art at the time of instant invention to have prepared the nutritional preparation of Killian et al. comprising particle size in the range of 500 micrometer to 2500 micrometer for better dissolution and oral availability motivated by the teachings of Freidman et. al. Regarding the amounts of various components, it is the position of the Examiner that it would have been within the purview of skilled artisan to have optimized the amounts of various components to come to the optimum level by doing experimental manipulations.

The references discussed above do not teach lysophosphatidyl choline.

'719 teach treatment of atherosclerosis by utilizing lysophosphatidylcholine and teaches average diameter to be from 100-150 nanometers, see abstract. The reference teaches that besides clogging of blood vessels, atherosclerosis also causes damage to kidneys, intestines etc. see column 1, lines 30-35. The reference also

teaches equivalency between phosphatidyl choline and other phospholipids which can be used to treat atherosclerosis, such as phosphatidylinositol, lysolecithin, and phosphatidylcholine, see column 6, lines 30-45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate lysophosphatidyl choline in the primary references for better health benefits because '719 teaches equivalency between phospholipids and their corresponding lyso forms. One would thus have been motivated to utilize lysophosphatidyl choline in place of lecithin in the teachings of primary reference with an expectation to have improved nutritional product which provides better bioavailability and gastrointestinal dissolution and also provides the improved physiological health benefits as taught by '719. Additionally, since Killian is directed to treatment of vascular diseases, it would have been further obvious to one of ordinary to utilize lysophosphatidylcholine as taught by '719 to treat vascular diseases such as athersclerosis.

'069 teaches methods and compositions comprising lysophosphatidylcholine and lecithin and other phospholipids in treating intestinal absorption of fats which improves absorption of dietary fats, see column 2, lines 65-67 and column3, lines 1-2. The reference provides equivalency between various phospholipids and lysophospholipids such as phosphatidylcholine and lysophosphatidylcholine, see column2, lines 15-25.

It would have been obvious to have utilized lysophopshatidylcholine in place of lecithin and other phospholipids to have better intestinal absorption of dietary fats because '069 teaches and provides equivalency between various phospholipids. One of

ordinary would have been further motivated to utilize lysophosphatidylcholine in a solid matrix of primary reference for better absorption, bioavailability and health benefits. From the teachings of the references, it is therefore apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Claims 35-48 and 50-52 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kiliaan et al. (WO 01/84961 A2) in view of Friedman (US pg pub 2003/0021881) and further in view of Ponroy (USP 6,069,138).

Kiliaan et al. discloses a nutritional preparation suitable for the prevention and/or treatment of vascular disorders, comprising long chain polyunsaturated fatty acids; phospholipids, the phospholipids contains at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol. The composition contains compounds which are a factor in methionine metabolism, containing at least one member selected from the group consisting of folic acid, vitamin B 12, vitamin B6, magnesium and zinc (mineral) see (abstract).

The preparation of the invention can be a pharmaceutical, dietetic as well as a nutritional preparation. The products can have the form of a liquid, powder, bar, cookie, sweetie, concentrate, paste, sauce, gel, emulsion, tablet, capsule, etc. to provide the daily dose of the bioactive components either as a single or in multiple doses (page 6,

lines 1-5). Triglyceride (a hydrophobic material) is listed on page 6, line 14. The composition contains zinc and copper (see page 9, lines 1-5). Kiliaan et al. discloses on page 12, various diseases and symptoms that can be treated are cognitive degeneration (thus improving mental fitness) and improper functioning associated with kidneys, liver, stomach etc. Another advantage of the composition disclosed is in normalizing plasma cholesterol levels (see page 6, lines 17-18).

Kiliaan discloses a capsule containing phospholipids comprised of phosphatidyl serine and phosphatidylcholine (acetone insoluble phospholipids); the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids. The composition of Kiliaan is administered to treat vascular disorders. The reference teaches that the composition can be in the form of tablet, powder, bar cookie or capsule, see page 6, lines 1-5. since the prior art teaches tablet and powder formulation, one would expect the matrix to be stable because prior art essentially teaches the claimed components.

While Killian teaches nutritional preparation can be in a tablet and powder form, Kiliaan does not specifically teach the claimed particle size. Friedman as discussed above teaches a nutritional preparation comprising solid matrix with particle size from 0.5mm to 2.5 mm (500 micrometer to 2500 micrometer) and discloses that the composition has improved gastrointestinal dissolution and oral availability, see page 2, paragraph [0023].

It would have been obvious to one of ordinary skill in the art at the time of instant invention to have prepared the nutritional preparation of Killian et al. comprising particle size in the range of 500 micrometer to 2500 micrometer for better dissolution and oral availability motivated by the teachings of Freidman et. al.

Regarding the amounts of various components, it is the position of the Examiner that it would have been within the purview of skilled artisan to have optimized the amounts of various components to come to the optimum level by doing experimental manipulations.

The references taught above do not disclose Sphingomyelin in the nutritional preparation.

Ponroy teaches use of phospholipids in therapy and dietetic composition, see abstract. The reference teaches importance of a composition comprising various phospholipids such as phosphatidylserine, phosphatidylcholine, sphingomyelin and lysophospholipids in improving the quality of nighttime sleep, alertness during the day as well as memory and learning skills, see column 3, lines 14-20 and examples in column 3 and 4.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to incorporate lysophospholipid or sphingomyelin in the nutritional preparation of Killian and Freidman for therapeutic benefits such as memory and learning capabilities associated with various phospholipids as taught by Ponroy's reference. It would have been further obvious to one of ordinary skill in the art to substitute

lysophosphatidylcholine in the teachings of Killian and Freidman because Ponroy teaches equivalency between phosphatidylcholine and lysophosphatidylcholine.

9. Claim 49 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Friedman (US PG Pub. 2003/0021881) in view of USP 6,312,719 and USP 6,426,069 as discussed above and further in view of JP 61078351, presented in IDS.

The teachings of the references discussed above do not include lecithin in the form of microcapsule.

JP teaches microcapsules comprising lecithin and coated with gelatin wherein the lecithin is prevented from being oxidized and deteriorated. The particle size is from 10-2000 micrometer, see abstract.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to include microcapsules comprising lecithin in the teachings of Killiaan in order to have stabilized product because JP teaches that such preparation helps in preventing deterioration and oxidation of the product. From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claim 49 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Kiliaan et al. (WO 01/84961 A2) in view of Friedman (US PG Pub. 2003/0021881) and further in view of USP 6,312,719 and USP 6,426,069 as discussed above and further in view of JP 61078351, presented in IDS.

The teachings of the references discussed above do not include lecithin in the form of microcapsule.

JP teaches microcapsules comprising lecithin and coated with gelatin wherein the lecithin is prevented from being oxidized and deteriorated. The particle size is from 10-2000 micrometer, see abstract.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to include microcapsules comprising lecithin in the teachings of Killiaan in order to have stabilized product because JP teaches that such preparation helps in preventing deterioration and oxidation of the product. From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

11. Applicant's arguments with respect to claims 35-52 have been considered but are moot in view of the new ground(s) of rejection.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612